DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Food and Drug Administration
Rockville MD 20857

SEP 28 1999

8452 '99 OCT -4 A9:26

Albert H. Meyerhoff, Esquire
Altshuler, Berzon, Nussbaum,
Berzon and Rubin
177 Post Street, Suite 300
San Francisco, CA 94108

Re: Docket No. 97P-0034
Comment No. CP1

Dear Mr. Meyerhoff:

We refer to your citizen petition dated January 27, 1997, on behalf of the Natural Resources Defense Council, together with the Alliance to End Childhood Lead Poisoning, Physicians for Social Responsibility, Public Citizen, the Sierra Club, and the American Public Health Association. The petition requests that FDA initiate rulemaking to limit the presence of lead in dietary calcium supplements and antacids to no more than 0.5 micrograms of lead in the recommended daily dose of these products.

FDA supports the concept that lead levels of calcium-containing products be as low as practicable. Therefore, FDA is actively investigating the feasibility of establishing lower limits of lead in calcium-containing products (see attached letter of March 11, 1999, from Yana Ruth Mille, Compendial Operations Staff, CDER, to Joseph G. Valentino, J.D., of the United States Pharmacopeal Convention, Inc. (USP)). However, at this time, we are unable to grant the specifics of your request in that the information in your petition does not provide a basis for FDA to take the actions requested by you in your petition. Therefore, in accordance with Title 21 of the Code of Federal Regulations Part 10.30(e)(3), this letter is to advise you that FDA is denying your petition, without prejudice.

If you have any questions regarding the petition, please refer to the docket number and comment number above, and submit all inquiries, in triplicate, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Sincerely yours,

for Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

Enclosure

97P-0034

PDN 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

HFD-360
CORRIGAN

MAR 11 1999

Joseph G. Valentino, J.D.
Senior Vice President and General Counsel
The United States Pharmacopeial
Convention, Inc.
12601 Twinbrook Parkway
Rockville, MD 20852

REF: 2-99-002-M

Dear Dr. Valentino:

This letter is in reference to the issue of lead levels in calcium-containing antacid drug products. FDA supports the lowest possible lead levels in calcium-containing products. In response to a December 8, 1998, inquiry from CDER's Division of Over-the-Counter Drug Products (DOTCDP), Ms. Susan S. Fiering, Esq., of California's Department of Justice provided us with additional information pertaining to the reduction of lead levels in calcium-containing drug products. (See enclosed letter of January 13, 1999, which summarizes the information provided by Ms. Fiering.)

We are aware of an April 22, 1998, letter from you to Dr. Yetley in which you wrote that, at an April 14, 1998, meeting of the USP Subcommittee on Nonprescription Drugs and Nutritional Supplements, the Subcommittee noted the limitations in analytical methodology which need to be considered especially if the methodology is to be used for regulatory purposes. Finally, you stated that the Subcommittee would, at some future time, consider "an alternative analytical method capable of determining lead content at very low levels, along with a lower practical limit." We urge you to investigate acceptable analytical methods for the determination of smaller amounts of lead in calcium-containing products. For your information, I have also attached a copy of the Consent Judgement in People v. Warner Lambert, et al, which includes the graphite furnace and the ICP-MS methods used in California to analyze lead levels in calcium-containing products. We would appreciate the USP Subcommittee's review of any analytical methods that may be used to establish a lower USP standard for lead in calcium-containing products.

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By dyp

We hope these comments will be helpful to the Nonprescription Drugs and Nutritional Supplements Subcommittee. Please feel free to contact me at 301-594-0104 or Ms. Helen Cothran (301-827-2287), the contact person for this topic in DOTCDP, if there are any questions. Use of the reference number provided above on any ensuing correspondence would be appreciated.

Sincerely yours,

Yana Ruth Mille

Yana Ruth Mille
Chief
Compendial Operations Staff, HFD-354
Office of Pharmaceutical Science
Center for Drug Evaluation & Research

Enclosures (2)

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: SEP 2 9 1999

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 97P-0034.

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. CP1

Charles J. Ganley, M.D.

Attachment